

REMARKS

Reconsideration of the above-identified application, in view of the amendments above and the remarks following, is respectfully requested.

Claims 5, 10-21, 23, 25, and 28-42 are now pending in this Application. Claims 25, 32, and 35 have been amended as discussed herein below. All claims stand rejected under 35 U.S.C. § 102.

Claim 25 has been, if anything, broadened by its amendment. Claims 32 and 35 have been amended to correct obvious, cosmetic, typographical errors.

Interview

Applicants thank the Examiner for the courtesy of an interview, at which were discussed the constructive election and the previous art rejection. The issue of constructive election will be discussed below, as will be the new rejection.

Restriction

The Examiner states that according to M.P.E.P. § 821.03, the new Claims 29-42 are considered to have been constructively elected out, as they are directed to an invention that is independent or distinct from the invention originally claimed. Specifically, Claim 5 is said to be directed at applying two non-excitatory pulses to the heart, while Claims 29 and 41 do not require one of the pulses to be non-excitatory.

Applicants respectfully disagree.

First, Claims 30-40 all depend on Claim 5, and thus, do not belong in the same group as Claims 29 and 41-42.

Second, Applicants refer the Examiner to the last part of M.P.E.P. § 821.03 (emphasis added), and suggest that the Examiner is comparing Claims 29 and 41 to the recently amended Claim 5, and not to the originally presented Claim 5:

“The practice set forth in this section is not applicable where a provisional election of a single species was made in accordance with M.P.E.P. § **803.02** and applicant amends the claims such that the elected species is cancelled, or where applicant presents claims that could not have been restricted

from the claims drawn to other elected
invention had they been presented earlier."

Applicants reproduce herewith original Claim 5:

5. Heart control apparatus, comprising circuitry for generating a non-excitatory stimulus, and stimulus application devices for applying to a heart or to a portion thereof said non-excitatory stimulus, wherein said circuitry for generating a non-excitatory stimulus generates a stimulus which is unable to generate a propagating action potential.

For comparison the current Claim 29 is provided, with added matter marked in bold.
(there is no deleted language):

29. Heart control apparatus, comprising:

a circuitry for generating a non-excitatory stimulus;

a sensor which measures a physiological activity; and

stimulus application devices for applying to a heart or to a portion thereof said non-excitatory stimulus **according to an electrification pattern which results in a desired activation profile;**

wherein said circuitry for generating a non-excitatory stimulus generates a stimulus which is unable to generate a propagating action potential, **configured for applying**

a first non-excitatory stimulus to a first portion of the heart, said first non-excitatory stimulus having a first effect on the biomechanical behavior of the first portion of the heart, and

a second stimulus to a second portion of the heart, said second stimulus having a second effect on the biomechanical behavior of the second portion of the heart, said first and second effects being different from each other,

wherein said desired activation profile defines a synchronization of the contractions of the left and right ventricles.

Thus, Claim 29 could have been drafted as a claim dependent on originally presented Claim 5, and could not have been restricted therefrom.

In summary, Applicants believe that Claims 30-40 should have been examined herewith. At least Claim 37 (that the two deliveries are different in duration), is clearly distinct from the art, even according to the Examiner's interpretation thereof. Thus, the next

Office Action cannot be final. In addition, the Examiner is respectfully requested to reconsider her position with respect to Claims 29, 41, and 42.

35 U.S.C. § 102 Rejections

The Examiner has rejected Claims 5, 10-21, 23, and 25 as being anticipated by Kieval, U.S. Patent No. 5,800,464 ("Kieval"). Applicants respectfully disagree, on several grounds. First, however, Applicants respectfully protest that the Examiner did not point at any specific locations in Kieval as teaching the claim limitations. Only an indication regarding not relating to arrhythmia is provided (Col. 1, lines 19-40 and Col. 3, lines 15-31), but these locations are all in the background section. It is possible that the Examiner meant Col. 4, lines 15-31, which relates to the second full paragraph of the summary. Confirmation is respectfully requested.

Applicants' grounds for disagreement include:

- (a) that the instant application has a priority date earlier than that of the cited art;
- (b) that the cited art does not have circuitry that generates two different stimuli; and
- (c) that the cited art does not, in fact, provide two different signals, also not via the modality suggested by the Examiner of using electrodes of different polarity in contact with the tissue.

As to point (a): The instant application claims priority, *inter alia*, to U.S. Provisional Application No. 60/026,392, dated September 16, 1996. Kieval is from October 1996.

The following is from page 5 of this provisional application:

It is a further object of some aspects of the present invention to provide a complete control system for the heart which includes controlling the pacing rate, refractory period, conduction velocity and mechanical force of the heart. Except for heart rate, each of these parameters may be locally controlled, i.e., each parameter will be controlled in only a segment of cardiac muscle. It should be noted that heart rate may also be locally controlled, especially with the use of fences which isolate various heart segments from one another, however, in most cases this is detrimental to the heart's pumping efficiency.

And this from page 18, thereof:

Another aspect of the invention relates to modifying the relation between the contraction of the left ventricle and the contraction of the right ventricle. In a healthy heart, increased contraction of the left ventricle causes an increase in the input to the right ventricle, which in turn causes the right ventricle to pump harder. Decreased left ventricular output reduces the right ventricular output in the same manner. Some times it may be desirable to modify the flow from one ventricle without a corresponding change in the flow from the other ventricle. This may be achieved by simultaneously controlling both ventricles, one control increasing the flow from one ventricle while the other control decreases the flow from the other ventricle. This modification will usually be practiced for short periods of time only, since the vascular system is a closed system.

Another aspect of the present invention relates to performing a complete suite of therapies using a single device. A controller in accordance with a preferred embodiment of the invention includes several therapies which it can apply to the heart, including for example, increasing contractility, defibrillation, fencing heart rate control and pacing. The controller senses (using physiological sensors) the state of the body and decides on an appropriate short-term therapy, for example, defibrillation to overcome fibrillation, increasing the heart rate to increase the cardiac outflow or applying fences to restrain a sudden arrhythmia. Additionally or alternatively, such a controller can change the applied control sequence in response to long term

Applicants respectfully submit that these sections, for example, support at least Claim 5.

As to point (b): Kieval is directed at a single type of stimuli – an anodal stimulation pulse provided before pacing. This can be seen, for example, at Col. 4, lines 15-31, where it is taught that the signal is optimally timed and delivered. The various alternatives described (e.g., Col. 4, lines 32-39) are not for different use in different locations, nor for different effect. Only one effect is taught – hyper-polarization of cells and possibly improved relaxation during diastole (Title, Abstract, Col. 4, lines 8-14).

As to point (c): The reason provided by the Examiner that Kieval has two different stimuli is that Kieval supposedly has effects caused by different polarity of his signal at different electrodes. Applicants respectfully disagree. Kieval teaches that it is desired to have only a single effect and teaches several ways of achieving such an equal effect over as much of the affected tissue as possible (Col. 7, lines 4-25). Any effects at cathodal electrodes (if any) appear to be negligent. In particular, the Examiner has not shown the specific suggestions of, for example, Claims 10, 11 or 12.

Applicants respectfully submit that the Examiner has not provided any specific rejection for any of the dependent claims, such as Claims 14, 19, 25, 28, or 30-40. This is another reason why the next rejection cannot be final.

Conclusion

Dependent claims not separately argued are patentable at least for reason of being dependent on an allowable independent claim. Applicants reserve the right to reintroduce canceled and amended claims and claim language in this or related application. It is believed that all the points raised by the examiner have been responded to and a notice of allowance is respectfully awaited.

Respectfully submitted,

/William H. Dippert/

William H. Dippert
Reg. No. 26,723
Attorney for Applicants
Phone: 914-286-2813 (Direct)

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Eckert Seamans Cherin & Mellott, LLC
10 Bank Street
White Plains, New York 10606

Phone: 914-949-2909
Fax: 914-949-5424